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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,543	12/05/2003	Karoline Bechtold-Peters	1/1149-1-C1	6244

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EXAMINER	
AZPURU, CARLOS A	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,543	BECHTOLD-PETERS ET AL.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the information disclosure statement file 12/05/2003,

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-11, 17-58 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11, 18-57 of copending Application No. 09/975,418. (US'418) This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The instant claims set out the same tiotropium powder with the same particle characteristics.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164

USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/975,418 (US'418) Although the conflicting claims are not identical, they are not patentably distinct from each other because US'418 sets out an inhalable powder comprising 0.04 to 0.8% tiotropium in admixture with a physiologically acceptable excipient, wherein the excipient consists of a mixture of coarser excipient with an average particle size of 15 to 80 um and finer excipient with an average particle size of 1 to 9 um, the proportion of the finer excipient constituting 1 to 20% of the total amount of excipient (see claim 1). The powder is made by mixing the coarser and finer particles, then mixing in the tiotropium (see claim 12). The powder may also be used to form a similar inhalable capsule (see claims 15 and 16). Further, the powder is used to treat the same diseases such as COPD (see claims 13 and 14). Therefore, those of ordinary skill would have expected similar therapeutic results in treatment of COPD from the instantly claimed invention given that the powder characteristics are the same. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant claims would have been obvious given the claims of US'418.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13, 17-24, 31-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold et al. in view of Ahmed.

Arnold et al disclose an inhalable powder which combines finer and coarser particles (See Abstract). The coarser particles range from a size of greater than 20 um to finer particles smaller than 10 um. The weight ratio of fine to coarse particles is between 1:99 and 95:5 (see col. 1, lines 55-57), which falls within the claimed ratio of 1 to 20 %for finer particles to total excipient. The proportion of active ingredient in these inhalable powders is 0.1 to 0.1 to about 5 mg of excipient mixture. So about 0.2%is found in the mixture, which falls within the claimed range of 0.4 to 0.8%, 0.48 and .096%, 0.5 and 1%. The quantity of preparation for each application is between 1 to 20 mg (see col.2, line 2). The excipients used may be monosaccharides, disaccharides, polysaccharides, polyalcohols and inorganic salts (see claim 3). Arnold et al clearly discloses the

type of inhalable powder and method of manufacturing it, as well as the inclusion of bioactives. The reference however lacks the teaching of the specific inclusion of tiotropium as the inhalable bioactive, as well as its use in the treatment of COPD and specifically asthma.

The Ahmed reference teaches that the treatment of asthma (See column 1, lines 1-67; col. 2, lines 1-6). Medications such as tiotropium bromide are specifically recited for this therapeutic use at col. 6, line 57. Therefore, it would have been well within the skill of the ordinary practitioner to use the inhalable powder formulation disclosed by Arnold et al and further to use tiotropium as the bioactive for its well know use in treating COPD and asthma in particular. Those of ordinary skill would have expected similar therapeutic results in the treatment of asthma from the instant formulation given the teachings of Arnold et al in view of Ahmed. Therefore, the instant formulation comprising coarse and fine particles in an inhalable powder formulation containing tiotropium would have been obvious in view of Arnold et al in view of Ahmed.

Claims 14-16, 25-34, 48 and 52-58 rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold et al in view of Ahmed, both further in view of Horhota et al.

Arnold et al disclose an inhalable powder which combines finer and coarser particles (See Abstract). The coarser particles range from a size of

greater than 20 um to finer particles smaller than 10 um. The weight ratio of fine to coarse particles is between 1:99 and 95:5 (see col. 1, lines 55-57), which falls within the claimed ratio of 1 to 20 %for finer particles to total excipient. The proportion of active ingredient in these inhalable powders is 0.1 to 0.1 to about 5 mg of excipient mixture. So about 0.2%is found in the mixture, which falls within the claimed range of 0.4 to 0.8%, 0.48 and .096%, 0.5 and 1%. The quantity of preparation for each application is between 1 to 20 mg (see col.2, line 2). The excipients used may be monosaccharides, disaccharides, polysaccharides, polyalcohols and inorganic salts (see claim 3). Arnold et al clearly discloses the type of inhalable powder and method of manufacturing it, as well as the inclusion of bioactives. The reference however lacks the teaching of the specific inclusion of tiotropium as the inhalable bioactive, as well as its use in the treatment of COPD and specifically asthma.

The Ahmed reference teaches that the treatment of asthma (See column 1, lines 1-67; col. 2, lines 1-6). Medications such as tiotropium bromide are specifically recited for this therapeutic use at col. 6, line 57. Dosing of this medicament is a skill of an ordinary practitioner according to the route of administration, and particular disease. Therefore, it would have been well within the skill of the ordinary practitioner to use the inhalable powder formulation disclosed by Arnold et al and further to use tiotropium as the bioactive within the claimed dosage amounts for its well know use in treating COPD and asthma in particular. Those of ordinary skill would have expected similar therapeutic results in the treatment of asthma from the instant formulation given the teachings of

Arnold et al in view of Ahmed. Therefore, the instant formulation comprising coarse and fine particles in an inhalable powder formulation containing tiotropium would have been obvious in view of Arnold et al in view of Ahmed.

Both references lack a teaching of using such a powder in an inhalant capsule. In a related reference, Horhota et al disclose that such capsules are commonly used to store powdered inhalant formulations (see col. 1, lines 25-67; col. 2, lines 1-62). Among the bioactives included in such formulations is tiotropium bromide). It would have therefore been within the skill of the ordinary practitioner to claim the instant formulation contained within an inhalant capsule given the teachings of Horhota et al, with an expectation of similar therapeutic results. The ordinary practitioner would have found it obvious to claim the powder formulation in view of Arnold et al in view of Ahmed, and would have further found it within their skill to place such a formulation within an inhalant capsule given the teachings of Horhota et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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